

117TH CONGRESS
1ST SESSION

H. R. 2870

To amend the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 2021

Mr. CARTER of Georgia (for himself and Ms. BLUNT ROCHESTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*

2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Essential Medicines

5 Strategic Stockpile Act of 2021”.

1 **SEC. 2. PILOT PROGRAM ON ENSURING MEDICATION SUP-**

2 **PLY STABILITY.**

3 Part D of the Public Health Service Act (42 U.S.C.

4 254b et seq.) is amended by adding at the end the fol-

5 lowing new subpart:

6 **“Subpart XIII—Ensuring Medication Supply Stability**

7 **“SEC. 340J. ENSURING MEDICATION SUPPLY STABILITY.**

8 “(a) AWARD OF CONTRACTS.—Beginning not later

9 than January 1, 2022, the Secretary shall award contracts

10 to eligible entities to each implement and test the effective-

11 ness of acquiring, maintaining, managing, and distrib-

12 uting a stockpile that—

13 “(1) consists of generic drugs at risk of short-

14 age; and

15 “(2) is of sufficient quantity to ensure that cus-

16 tomers in the United States have access to such

17 drugs for at least 6 months (as specified by the Sec-

18 retary based on the historic demand for those

19 drugs).

20 “(b) SELECTION OF DRUGS.—

21 “(1) IN GENERAL.—The Secretary shall—

22 “(A) select not more than 50 drugs that

23 may be included by eligible entities in a stock-

24 pile pursuant to a contract under this section;

25 and

1 “(B) maintain an up-to-date list of such
2 drugs; and

3 “(C) make such list publicly available.

4 “(2) CHOICE OF ELIGIBLE ENTITIES.—A con-
5 tract awarded to an eligible entity under this section
6 need not require the stockpile of the eligible entity
7 to include all 50 drugs listed pursuant to paragraph
8 (1).

9 “(c) SUFFICIENT QUANTITY.—For each generic drug
10 listed pursuant to subsection (b)(1), the Secretary shall
11 specify the quantity of such drug that is sufficient to en-
12 sure that consumers in the United States have access to
13 such drug for at least 6 months.

14 “(d) DURATION; LIQUIDATION OF INVENTORY.—

15 “(1) DURATION.—A contract awarded under
16 this section shall be for a term of no more than 3
17 years.

18 “(2) LIQUIDATION OF INVENTORY.—A drug
19 held in a stockpile pursuant to a contract under this
20 section may be liquidated by the eligible entity at the
21 end of the period of the contract.

22 “(e) STOCKPILE REQUIREMENTS.—

23 “(1) ENSURING AVAILABILITY OF UNEXPIRED
24 PRODUCTS.—Each eligible entity with a contract

1 under this section for a stockpile of generic drugs at
2 risk of shortage shall—

3 “(A) ensure that each drug maintained in
4 the stockpile has an expiration date at least 1
5 year beyond the current date; and

6 “(B) to comply with subparagraph (A)—

7 “(i) sell drugs in the stockpile through
8 normal commercial channels and replace
9 those drugs; or

10 “(ii) if there is no commercial market
11 for a drug in the stockpile, dispose of the
12 drug and report such disposal to the Sec-
13 retary.

14 “(2) MANAGEMENT OF STOCKPILE.—

15 “(A) IN GENERAL.—The Secretary shall
16 ensure that—

17 “(i) collectively, the eligible entities
18 with contracts under this section for a
19 stockpile of generic drugs at risk of short-
20 age acquire, not later than 6 months fol-
21 lowing the date set in such contracts, and
22 maintain thereafter, a 6-month supply of
23 such drugs; and

24 “(ii) the 6-month supply required by
25 clause (i) is in addition to the average lev-

1 els of inventory held by eligible entities
2 over the previous year for the respective
3 drugs.

4 “(B) INVENTORY MANAGEMENT.—Each el-
5 igible entity with a contract under this section
6 for a stockpile of generic drugs at risk of short-
7 age shall manage inventory to ensure that
8 drugs in the stockpile are efficiently cycled to
9 the commercial market.

10 “(C) ANNUAL AUDITS.—Not more than
11 annually, the Secretary may request a physical
12 audit count of the inventories of all eligible enti-
13 ties with a contract under this section to vali-
14 date that each such entity is maintaining the
15 appropriate amount of stockpiled inventory.

16 “(3) REPORTING.—Each eligible entity with a
17 contract under this section shall submit reports at
18 such time and in such manner as the Secretary may
19 require regarding—

20 “(A) current inventory levels of stockpiled
21 drugs at a drug level;

22 “(B) indicators of current inventory levels
23 of stockpiled drugs relative to acceptable mini-
24 mums; and

1 “(C) such other matters as the Secretary
2 determines appropriate.

3 “(f) CONTRACT TERMS.—

4 “(1) PAYMENT OF MONTHLY FEES FOR MAN-
5 AGEMENT.—Subject to paragraph (2), the Secretary
6 shall pay to each eligible entity with a contract
7 under this section for a stockpile of generic drugs at
8 risk of shortage appropriate monthly fees for the
9 management of the stockpile.

10 “(2) PAYMENT CONDITIONED ON STOCKPILE
11 ADEQUACY.—

12 “(A) IN GENERAL.—Except as provided in
13 subparagraph (B), each contract with an eligi-
14 ble entity under this section shall provide that
15 no payment under the contract may be made
16 until the entity demonstrates to the Secretary
17 that the entity has stockpiled such portion of
18 the total quantity of drugs to be stockpiled
19 under the contract as the Secretary determines
20 to be acceptable for payment.

21 “(B) EXCEPTIONS FOR ADVANCE PAY-
22 MENTS.—

23 “(i) IN GENERAL.—A contract under
24 this section may provide that, if the Sec-
25 retary determines (in the Secretary’s dis-

cretion) that an advance payment, partial payment for significant milestones, or payment to increase capacity is necessary to ensure success of the terms of the contract, the Secretary shall pay, in advance of delivery, an amount not to exceed 10 percent of the total contract amount to be paid to the eligible entity by the Secretary pursuant to the contract over the full period of the contract.

“(ii) COST OF CAPITAL.—A contract under this section may provide for payments to compensate the contracting eligible entity for additional capital requirements related to the additional inventory to be maintained.

17 “(iii) TIMING.—The Secretary shall,
18 to the extent practicable, make any deter-
19 mination under clause (i) to make an ad-
20 vance payment at the same time as the
21 issuance of a solicitation.

22 “(iv) REPAYMENT.—If the Secretary
23 makes an advance payment pursuant to
24 clause (i), the Secretary shall require the
25 eligible entity receiving such advance pay-

3 “(3) TERMINATION.—Nothing in this section
4 shall be construed as affecting the rights of eligible
5 entities under provisions of statute or regulation (in-
6 cluding the Federal Acquisition Regulation) relating
7 to the termination of contracts for the convenience
8 of the Government.

9 “(g) CONGRESSIONAL OVERSIGHT.—

“(1) INDEPENDENT EVALUATION AND REPORT.—Not later than 1 year after the date of enactment of this section and annually thereafter, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate congressional committees a report, concerning the program under this section.

17 “(2) CONTENTS OF REPORT.—The report under
18 paragraph (1) shall review, assess, and provide rec-
19 ommendations, as appropriate, on the following:

“(A) Details on likely costs and resultant savings as compared to a stockpiling method that does not incorporate perpetual inventory cycling.

1 “(B) Identification of drawdowns from the
2 stockpile, as evidence of market shortage avoid-
3 ance.

4 “(C) The allocation of drugs included in
5 the stockpiles funded pursuant to this section to
6 the customers of the eligible entities with con-
7 tracts under this section.

8 “(D) The degree to which eligible entities
9 with contracts under this section fulfilled their
10 obligations under such contracts.

11 “(h) DEFINITIONS.—In this section:

12 “(1) The term ‘eligible entity’ means an entity
13 that meets each of the following criteria:

14 “(A) The entity is licensed or registered in
15 accordance with applicable Federal and State
16 law and in good standing with respect to such
17 licensure or registration.

18 “(B) If the entity is not a manufacturer,
19 the entity agrees—

20 “(i) to purchase all drugs to be main-
21 tained in its stockpile funded under this
22 section directly from the manufacturers of
23 the drugs or the exclusive distributors of
24 such manufacturers; or

1 “(ii) in the case of an entity that is a
2 co-op or chain pharmacy warehouse—

3 “(I) to purchase drugs to be
4 maintained in its stockpile funded
5 under this section from an authorized
6 distributor; and

7 “(II) distribute those drugs only
8 to its member pharmacies.

9 “(C) The entity sells more than 90 percent
10 of its drugs to dispensers.

11 “(D) The entity agrees to distribute inven-
12 tory from its stockpile funded under this section
13 only to wholesale distributors or dispensers that
14 are customers of the entity.

15 “(2) The term ‘generic drug at risk of shortage’
16 means a drug (as defined in section 201 of the Fed-
17 eral Food, Drug, and Cosmetic Act) that—

18 “(A) is approved pursuant to section
19 505(j) of such Act;

20 “(B) is included in the list of essential
21 medicines published by the Food and Drug Ad-
22 ministration;

23 “(C) is included, at any point during the
24 preceding 36 months, on the drug shortage list

1 in effect under section 506E of the Federal
2 Food, Drug, and Cosmetic Act; and

3 “(D) is manufactured by 3 or fewer per-
4 sons that are registered under section 510 of
5 the Federal Food, Drug, and Cosmetic Act for
6 purposes of such manufacture.

7 “(i) AUTHORIZATION OF APPROPRIATIONS.—To
8 carry out this section, there is authorized to be appro-
9 priated \$120,000,000 for fiscal years 2022 through 2024,
10 to remain available until expended.”.

